

INFORMATION DISCLOSURE	Complete if Known		
STATEMENT BY APPLICANT	Application Numb r	09/816,839	
OTATEMENT BY APPEICANT	Filing Dat	MARCH 23, 2001	
(Use as many sheets as necessary)	First Named Inventor	Michael FUNG, et al.	
(order to many choose us necessary)	Group Art Unit	1648 1644	
1 4	Examiner Name Vander	SE NOT YET ASSIGNED	
SHEET OF OF	Attorney Docket Number	TNX 00-04	

Examiner	U.S. Docum	nents	U.S. Patent	Date of Publication of	Pages, Columns, Lines,	
Initials	Number Kind Code (if known)		Document Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	
B	5,225,539	B1	G. WINTER	July 6, 1993		
	5,530,101	B1	C. QUEEN, et al.	June 25, 1996		
	4,946,778	B1	LADNER, et al.	AUG. 7, 1990		

FOREIGN DOCUMENTS								
Examiner Initials	Foreign Patent Documents Office Number Kind Code (if known)				Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
Examiner Signature		2.6	2	Pu	10/	Date Considered	2/21/05	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) Inside this box	+

PTO/SB/08A (08-00)

٦,

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

use as many sheets as necessary)

Complete if Known 09/816,839 Applicati n Numb r MARCH 23, 2001 Filing Dat First Named Inv ntor Michael FUNG, et al. 1845 1644 **Group Art Unit** Examiner Name VANDENVE67 NOT YET ASSIGNED

Attorney Docket Number TNX 00-04

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Examiner Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of Initials No. the item (book, magazine, journal, serial, symposium, catalog, etc.), date, volume-issue number(s), page(s). M. MATSUSHITA, "The Lectin Pathway of the Complement System", Microbiol. Immunol. 40(12):887-893 1. 2 M. MATSUSHITA, et al., "MASP-1 (MBL-Associated Serine Protease-1)", Immunobiol. 199:340-347 (1998). C. SUANKRATAY, et al., "Requirement for the Alternative Pathway as well as C4 and C2 in Complement-3 Dependent Hemolysis via the Lectin Pathway, J. Immunol. 160:3006-3013 (1998). Y. ZHANG, et al., "Lysis via the Lectin Pathway of Complement Activation: minireview and lectin pathway 4 enhancement of endotoxin-initiated hemolysis", Immunopharmacol. 42:81-90 (1999). Y. ZHANG, et al., "Calcium-Independent Haemolysis via the Lectin Pathway of Complement Activation in the 5 Guinea-Pig and Other Species", Immunol. 97:686-692 (1999). 6 HANS-PETER HEINZ, et al., "Monoclonal Antibodies Against Components of the Classical Pathway of Complement, Complement Inflamm. 6:166-174 (1989). V.M. HOLERS, "Complement", IN: CLINICAL IMMUNOLOGY: PRINCIPLES AND PRACTICE, R.R. RICH 7 Ed., MOSBY PRESS, 1996, pp. 363-391. VORUP-JENSEN, et al., *MASP-2, the C3 Convertase Generating Protease of the MBLectin Complement 8 Activating Pathway", Immunobiol. 199: 348-357 (1998). C. SUANKRATAY, et al., "Complement Regulation in Innate Immunity and the Acute-Phase Response: 9 Inhibition of Mannan-Binding Lectin-Initiated Complement Cytolysis of C-Reactive Protein*, Clin. Exp. Immunol. 113:353-359 (1998). C. SUANKRATAY, et al., "Mechanism of Complement-Dependent Haemolysis via the Lectin Pathway: Role of 10 the Complement Regulatory Proteins", Clin. Exp. Immunol. 117: 442-448 (1999). R. SCHLINDER, et al., "Recombinant C5a Stimulates Transcription Rather Then Translation of Interleukin-1 (IL-1) and Tumor Necrosis Factor: Translational Signal Provided by Lipopolysacchande or IL-1 Itself, Blood 11 76:1631-1638 (1990) T. WIEDMER et al., *Participation of Protein Kinases in Complement C5b-9-Induced Shedding of Platelet 12 Plasma Membrane Vesicles", Blood 78:2880-2886 (1991). M. P. FLETCHER, et al., "C5a-Induced Myocardial Ischemia: Role for CD18-Dependent PMN Localization 13 and PMN-Platelet Interactions", Am. J. Physiol. 265:h1750-1761 (1993). S. NAGASAWA, et al., *Cleavage of C2 by C1s into Antigenically Distinct Fragments C2a and C2b: 14 Demonstration of Binding of C2b to C4b*, Proc. Natl. Acad. Sci. (USA) 74:2998-3001 (1977). Examiner Date Signature Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please time a plus star (1) to the star to	_
Please type a plus sign (+) inside this box	+

INFORMATION DISCLOSURE	C mplete if Known		
E JC STATEMENT BY APPLICANT	Applicati n Numb r	09/816,839	
(Useas many sheets as necessary)	Filing Dat	MARCH 23, 2001	
	First Named Inv nt r	Michael FUNG, et al.	
	Gr up Art Unit	1645-1644	
2 3/	Examin r Nam Kader est	NOT YET ASSIGNED	
SHEET 3 OF 4	Attorney Docket Number	TNX 00-04	

Examiner Initials Cite No. Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate) of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s),		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),	Т2
PV	15	E. I. STENBAEK, et al., "Human Complement Component C2: Production and Characterization of Polyclonal and Monoclonal Antibodies Against C2", Mol. Immunol. 23:879-886 (1986).	
	16	T. J. OGLESBY, et al., "Evidence for a C4b Binding Site on the C2b Domain of C2", J. Immunol. 141:926-931 (1988).	
	17	Y. WANG, et al., "Amelioration of Lupus-Like Autoimmune Disease in NZB/W F ₁ Mice After Treatment With a Blocking Monoclonal Antibody Specific for Complement Component C5", <i>Proc. Natl. Acad. Sci.</i> (USA), 1996, 93:8563-8568	
	18	C. S. RINDER, et al., "Blockade of C5a and C5b Generation Inhibits Leukocyte and Platelet Activation During Extracorporeal Circulation", <i>J Clin. Invest.</i> 96:1564-1572 (1995).	
	19	J. C. K. FITCH, et al., "Pharmacology and Biological Efficacy of a Recombinant, Humanized, Single-Chain Antibody C5 Complement Inhibitor in Patients Undergoing Coronary Artery Bypass Graft Surgery with Cardiopulmonary Bypass", Circulation 100:2499-2506 (1999).	
	20	H. L. LAZAR, et al., "Total Complement Inhibition: An Effective Strategy to Limit Ischemic Injury During Coronary Revasculaization on Cardiopulmonary Bypass", Circulation 100:1438-1442 (1999).	
	21	T. J. KROSHUS, et al., "Complement Inhibition with an Anti-C5 Monoclonal Antibody Prevents Acute Cardiac Tissue Injury in an Ex Vivo Model of Pig-To-Human Xenotransplantation", <i>Transplantation</i> 60:1194-1202 (1995).	
	22	J. W. HOMEISTER, et al., "Soluble Complement Receptor Type 1 Prevents Human Complement-Mediated Damage of the Rabbit Isolated Heart", J. Immunol. 150: 1055-1064 (1993).	
	23	H. F. WEISMAN, et al., "Soluble Human Complement Receptor Type 1: In Vivo Inhibitor of Complement Suppressing Post-Ischemic Myocardial Inflammation and Necrosis", Science 249:146-151 (1990).	
	24	E. A. AMSTERDAM, et al., "Limitation of Reperfusion Injury by a Monoclonal Antibody to C5a during Myocardial Infarction in Pigs", <i>Am. J. Physiol.</i> 268: H448-H457 (1995).	
	R. RABINOVICI, et al., "Role of Complement in Endotoxin/Platelet-Activating Factor-Induced Lung Injury", J. Immunol. 149:1744-1750 (1992).		
	26	B. P. MORGAN, "Clinical Complementology: Recent Progress and Future Trends", Eur. J. Clin. Invest. 24:219-228 (1994).	
	27	S. M. CANFIELD, et al., "The Binding Affinity of Human IgG for its High Affinity Fc Receptor is Determined by Multiple Amino Acids in the C _H 2 Domain and is Modulated by the Hinge Region", <i>J. Exp. Med.</i> 173:1483-1491 (1991).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box +

EINE RMATION DISCLOSURE	Complet if Known	
STATEMENT BY APPLICANT	Application Number 09/816,839	_
OTATEMENT BY APPLICANT	Filing Dat MARCH 23, 2001	_
(I Ise as many sheets as necessary)	First Nam d Inv nt r Michael FUNG, et al.	_
(Use as many sheets as necessary)	Gr up Art Unit / -1645 /644	
	Examiner Name Vander Vest-NOT YET ASSIGNED	
SHEET 4 OF 4	Attorney Docket Number TNX 00-04	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),	T 2
m	28	KOHLER AND MILSTEIN, "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity", Nature 256: 495-497 (1975).	
	29	Y. XU, et al., "Residue at Position 331 in the IgG1 and IgG4 C _H 2 Domains Contributes to Their Differential Ability to Bind and Activate Complement", <i>J. Biol. Chem.</i> 269:3469-3474 (1994).	
	30	V. L. PULITO, et al., "Humanization and Molecular Modeling of the Anti-CD4 Monoclonal Antibody, OKT4A", <i>J. Immunol.</i> 156:2840-2850 (1996).] ,
	31	L. RIECHMANN, et al., "Reshaping Human Antibodies for Therapy", Nature 332:323-327 (1988).	
	32	M. J. EVANS, et al., "Rapid Expression of an Anti-Human C5 Chimeric Fab Utilizing a Vector That Replicates in COS and 293 Cells", <i>J. Immunol. Meth.</i> 184:123-138 (1995).	
	33	S.K. DATTA, "Murine Lupus", <i>Meth. Enzymol.</i> 162:385-413 (1988).	
	34	D. J. SALVANT, et al., "Experimental Glomerulonephritis", Meth. Enzymol. 162:421-461 (1988).	
	35	Y. WANG, et al., "Anti C5 Monoclonal Antibody Therapy Prevents Collagen-Induced Arthritis and Ameliorates Established Disease", <i>Proc. Natl. Acad. Science</i> (USA) 92:8955-8959 (1995).	
	36	M. S. MULLIGAN, et al., "Protective Effects of Soluble CR1 in Complement- and Neutrophil-Mediated Tissue Injury", J. Immunol. 148:1479-1485 (1992).	
Examiner Signature	6	5-P-12- Date 2/21/05	<u>. </u>

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.